IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA MISSOULA DIVISION

BNSF RAILWAY COMPANY, on behalf of THE UNITED STATES OF AMERICA, CV 19–40–M–DLC

Plaintiff,

ORDER

VS.

CENTER FOR ASBESTOS RELATED DISEASE, INC.,

Defendant.

Before the Court is Defendant Center for Asbestos Related Disease, Inc.'s ("CARD") Motion for Summary Judgment (Doc. 71) and Plaintiff BNSF Railway Company's ("BNSF") Motion for Partial Summary Judgment (Doc. 78). For the reasons discussed below, CARD's motion (Doc. 71) is GRANTED in part and DENIED in part; BNSF's motion (Doc. 78) is DENIED in full.

BACKGROUND

BNSF brought this *qui tam* action, pursuant to 31 U.S.C. § 3730, alleging that CARD violated the False Claims Act ("FCA"), §§ 3729(a)(1)(A), (B), and (G). (Doc. 66 at 49–54.) BNSF claims that CARD violated the FCA by knowingly presenting or causing to be presented: (1) "false or fraudulent claims for

payment or approval to the federal government;" (2) "a false record or statement material to a false or fraudulent claim;" and (3) "false records or statements material to an obligation to pay or transmit money or property to the government." (*Id.*) BNSF alleges that CARD submitted these false statements through Environmental Health Hazards Medicare Coverage ("EHH Coverage") forms to the Social Security Administration ("SSA"), bills to Medicare for opioid and other drug prescriptions, and grant applications and reports to the American Toxic Substances Disease Registry ("ATSDR") and Centers for Disease Control and Prevention. (*See id.* at 48–54.)

DISCUSSION

This Court can resolve an issue summarily if "there is no genuine dispute as to any material fact" and the prevailing party is "entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Material facts are those which may affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is genuine when there is sufficient evidence for a reasonable factfinder to return a verdict for the other party. *Id.* If the moving party meets its initial responsibility, the burden then shifts to the opposing party to establish that a genuine issue of fact exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

CARD moves for summary judgment on all claims raised in BNSF's Third

Amended Complaint. (Doc. 71.) CARD argues that BNSF cannot meet its burden under the FCA, and therefore, CARD is entitled to judgment as a matter of law. (Doc. 72 at 22.) CARD also argues that BNSF's claims fall outside the statute of limitations. (*Id.* at 30.)

BNSF moves for partial-summary judgment on their claim that CARD submitted false or fraudulent EHH Coverage forms to the SSA on behalf of "112 patients who CARD knows have no diagnosis of asbestos-related disease." (Doc. 79 at 4; *see also* Doc. 66-1 at 2–4 tbl. 3.)

A claim under the FCA requires a showing of: (1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, (4) causing the government to pay out money or forfeit moneys due. *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017); *see* 31 U.S.C. § 3729(a). The scienter requirement may be met where a defendant acts knowingly, with deliberate ignorance, or with reckless disregard. 31 U.S.C. § 3729(b)(1); *see also Winters ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1114 (9th Cir. 2020).

I. False Claims for Medicare Payment

Clinical opinions may constitute "false statements" under the FCA if the judgment or opinion "is not honestly held, or if it implies the existence of facts . . . that do not exist." *Winters*, 953 F.3d at 1119. "[A]n opinion may carry with it an

implied assertion, not only that the speaker knows no facts which would preclude such an opinion, but that he does know facts which justify it." *Id.* at 1117 (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 191 (2015)).

CARD argues that because the diagnostic opinions of CARD physicians are "based on the American Thoracic Society 2004 Guidelines" ("ATS Guidelines") and are "honestly held" they "cannot be false statements under the FCA." (Doc. 72 at 24.) CARD also argues that because "the diagnostic opinions of the CARD providers here are 'honestly held' and soundly based on the decades of extensive medical research and peer reviewed literature on the subject of Libby asbestos-related disease," the scienter requirement cannot be met. (*Id.* at 27.) Finally, regarding materiality, CARD argues that "the actions of [the] SSA indicate that it is certainly aware of how CARD staff fill out EHH checklists, since [the] SSA created the checklists . . . provided CARD with the checklists . . . [and] CARD staff continue to work closely with [the] SSA." (*Id.* at 29.)

BNSF responds that CARD physicians did not follow the ATS Guidelines for diagnosing individuals when certifying at least 112 claimants for EHH Coverage, and therefore, CARD physicians falsely stated that these 112 patients had been *diagnosed* with an asbestos-related condition. (Doc. 92 at 26–28; *see also* Doc. 66-1 at 2–4 tbl. 3.) BNSF also argues that on at least two occasions

CARD allowed non-physicians to certify patients as eligible for EHH Coverage.

(Doc. 92 at 28–29; Doc. 66-1 at 1 tbl. 1.) Lastly, BNSF argues that CARD physicians have provided "prescriptions for opioid pain medications . . . [that] were not medically necessary." (Doc. 92 at 20.)

The crux of each Party's argument centers on the meaning of "diagnose" as that term is used in the Affordable Care Act's ("ACA") provisions providing EHH Coverage. The ACA provides EHH Coverage to individuals who have been "diagnosed" with "[a]sbestosis, pleural thickening, or pleural plaques *as established by* . . . interpretation by a 'B Reader' qualified physician of a plain chest x-ray *or* interpretation of a computed tomographic radiograph of the chest by a qualified physician." 42 U.S.C. § 1395rr-1(e) (emphasis added).

CARD argues that they are following the SSA and ACA's instructions by certifying individuals for EHH Coverage where there has only been an interpretation by a "B Reader" qualified physician of a plain chest x-ray, although this is not a "diagnosis" under the ATS Guidelines. (*See* Doc. 72 at 23; *see also* Doc. 96 at 4–5; Doc. 98 at 2.) However, CARD has not provided a statement from the SSA supporting their argument that the SSA is fully informed as to CARD's practices regarding EHH Coverage certification. BNSF argues that CARD has been falsely or fraudulently certifying patients for EHH Coverage and misrepresenting their own practices to the SSA. (*See* Doc. 92 at 10–13; *see also*

Doc. 79 at 9.) However, neither party has produced sufficient evidence to justify granting summary judgment on this issue.

Accordingly, the Court DENIES CARD's Motion for Summary Judgment (Doc. 71) on the EHH Coverage forms claim and DENIES BNSF's Motion for Partial Summary Judgment (Doc. 78) on the same claim.

II. False Claims in Grant Applications and Reports

BNSF raises several claims regarding CARD's grant applications and reports for federal funds. First, BNSF claims that CARD falsely reported a dissention rate of 6%, when in reality it is closer to 70%. (Doc. 66-1 at 33.) Second, BNSF claims that CARD knowingly submitted incorrect information by stating that "CARD uses Outside Radiology Reads to ensure Accuracy," that "CARD's Peer-review program is used to ensure accuracy of reads and 'quality control," and by suggesting that CARD "follows the [ACA] rule that a diagnosis of asbestos related disease is required to obtain Medicare benefits." (*Id.*) Third, BNSF claims that CARD fraudulently acquired "\$5,500 'for CT Scans at CARD" as part of a grant sub-award from the Mount Sinai School of Medicine ("Mt. Sinai"), although "[t]here has never been a CT scanner at CARD." (*Id.* at 34.)

CARD responds that it "never claimed a 6% dissention rate between CARD providers and B Readers," but rather, "CARD reported a 47% diagnosis rate for CARD providers, a 41% CT abnormal positivity rate for B Readers, and a 63% CT

abnormal positivity rate for CARD providers." (Doc. 96 at 12.) CARD also argues that "ATSDR is aware of the various rates of diagnosis and CT abnormality positivity rates," (*id.* at 6), and that BNSF is conflating "B reader panel differentiation rates that are reported to ATSDR with [Family Nurse Practitioner] Boltz's estimate of Dr. Becker's dissention rate with Dr. Black, which is not report to ATSDR," (*id.* at 9).

CARD also contends that ATSDR staff and CARD staff have worked closely together on CARD's quarterly and annual reports and budget justifications. (Doc. 72 at 28.) CARD states that "it is clear from the actions of ATSDR continuing to fund CARD"—even after the United States Department of Health and Human Services' Office of the Inspector General ("HHS OIG") investigated CARD in 2015 and 2019—and "providing CARD with supplemental funding during the pendency of BNSF's litigation" proves that "any alleged false statements are not material." (*Id.* at 28–29.) CARD also reiterates their arguments regarding EHH Coverage certification discussed above, as it relates to the alleged false claims for the grant awards. (*Id.* at 29–30.)

Regarding the Mt. Sinai grant sub-award, CARD explains that there has never been a CT scanner at CARD and "[t]he term 'CT scans at CARD' was used to differentiate between a cohort of CT scans at Mount Sinai and a cohort of CT scans at CARD." (*Id.* at 21.) CARD also provided a declaration from the

"Principle Investigator" on the research program that granted CARD the \$5,500 sub-award, confirming CARD's explanation and further stating that "[i]t was clear that CARD did not have a CT scanner." (Doc. 96-1 at 2.)

BNSF argues that "neither the SSA nor ATSDR has complete and accurate information on which to base its decision to grant Medicare, or continue funding CARD's grant." (Doc. 92 at 39.) "ATSDR's continued funding of CARD's grant is predicated upon CARD's following the ATS [G]uidelines in diagnosing patients. . . . [But], CARD's failure to comply with the ATS [G]uidelines has not been reported to ATSDR." (*Id.* at 40.)

The record clearly establishes that CARD did not falsely or fraudulently obtain the \$5,500 grant sub-award from Mt. Sinai. However, CARD has not met their burden of showing no genuine issue of material fact exists on the remaining claims. Whether CARD submitted false or fraudulent information with scienter, what the SSA and ATSDR knew or did not know, and whether any false or fraudulent claims were material all remain questions of fact.

Accordingly, the Court GRANTS CARD's motion (Doc. 71) with respect to the claim that CARD falsely or fraudulently procured \$5,500 in a grant sub-award from Mt. Sinai and DENIES the motion with respect to all other claims.

III. Statute of Limitations

The FCA contains two limitations periods that apply to "a civil action

brought under section 3730." 31 U.S.C. §§ 3731(b); see also Cochise Consultancy, Inc. v. United States ex rel. Hunt, 139 S. Ct. 1507, 1510, 1512 (2019). First, the action must be brought within six years after the alleged statutory violation occurred. § 3731(b)(1). Second, the action must be brought within three years after "the official of the United States charged with responsibility to act" knew or reasonably should have known the relevant facts, but not more than ten years after the alleged violation occurred. § 3731(b)(2). "Whichever period provides the later date serves as the limitations period." Cochise, 139 S. Ct. at 1510; see also § 3731(b). The FCA's limitation periods apply equally to qui tam actions. Cochise, 139 S. Ct. at 1510. Although the Ninth Circuit has not addressed which government officials may qualify as the "official charged with responsibility to act," it has held that "the private person who initiates the qui tam suit cannot be deemed the official of the United States." Id. Other courts have concluded that the official must be within the United States Department of Justice ("DOJ"). See, e.g., United States v. Carell, 681 F. Supp. 2d 874, 881 (M.D. Tenn. 2009); United States v. Village of Island Park, 791 F. Supp. 354, 362 (E.D. N.Y. 1992); *United States v. Tech Refrigeration*, 143 F. Supp. 2d 1006, 1009 (N.D. III. 2001).

CARD argues that the three-year period is applicable and began to run in 2015 when complaints were filed with the HHS OIG against Dr. Black for "over

diagnosing patients with asbestos." (Doc. 72 at 30–31; *see also* Doc. 74-40 at 3.) Thus, CARD argues that the claims here are barred because they were filed after the 3-year period ran. (Doc. 72 at 31.)

BNSF responds that the statute of limitations analysis is a "fact-dependent matter, and CARD has presented insufficient facts." (Doc. 92 at 42.) BNSF argues that the statute of limitations should be, at minimum, six years, as this would provide the later date for claims to be filed. (*Id.*) BNSF then agues that equitable tolling should be applied to increase the statute of limitations to ten years because CARD has not presented sufficient facts demonstrating that the 2015 complaint to the HHS OIG and subsequent investigation provided "the official of the United States charged with responsibility to act" with "facts material to the right of action" to start the time clock. (*Id.* at 42–43.)

Determining what the responsible government official knew or should have known is "a complex factual determination to be made by the [Court]." *United States ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d 69, 78 (D.D.C. 2003) (quoting *United States v. Hess*, 194 F.3d 1164, 1175 (10th Cir. 1999)). It is known that the HHS OIG requested specific materials relevant to this case as part of their 2015 investigation, including "CARD's grant application, quarterly reports related to the grant, and the names and contact info for the expert B readers and radiologists reviewing radiographs/CTs for CARD." (Doc. 74-37 at 4.) It is also known that

the HHS OIG discussed their 2015 investigation with the prosecutor's office. (*See* Doc. 74-40 at 2). However, as BNSF points out, "CARD present[ed] no facts showing that the government obtained any patient EHH forms, patient medical records[,] or CARD's Master Data Set[—]all records which ultimately led to the discovery of [the alleged] fraud in this case." (Doc. 92 at 43.) Accordingly, the Court cannot conclude that the claims raised by BNSF are time-barred based on the 2015 HHS OIG investigation.

BNSF filed this action on March 6, 2019. (*See* Doc. 1.) BNSF claims that it became aware of the alleged violations in 2018 and subsequently reported them to the HHS OIG. (*See* Doc. 74-42 at 4; *see also* Doc. 72 at 4.) The HHS OIG requested that the SSA's Office of the Inspector General ("SSA OIG") begin a review of CARD based on BNSF's "*qui tam* referral," and the SSA OIG began its review on September 9, 2019. (*Id.*) The earliest alleged violation in BNSF's Third Amended Complaint occurred on May 18, 2010 (Doc. 66-1 at 7). Accordingly, the three-year limitations period would provide the later date and applies here. BNSF filed this action within the three-year time period—regardless of whether the "government official with responsibility to act" is within the HHS OIG, SSA OIG, or DOJ—and within ten years of the earliest alleged violation. Thus, this action is not barred by the statute of limitations.

Accordingly, IT IS ORDERED that CARD's motion (Doc. 71) is

GRANTED in part as to BNSF's claim that CARD was falsely awarded a \$5,500 grant sub-award from Mt. Sinai and DENIED as to all remaining claims.

IT IS FURTHER ORDERED that BNSF's motion (Doc. 78) is DENIED in full.

IT IS FURTHER ORDERED that the trial in this matter is RESET for June 12, 2023, at 9:00 a.m. in the Russell Smith Federal Courthouse in Missoula, Montana. The following deadlines are reset as follows:

Attorney Conference to Prepare

Final Pretrial Order: week of May 22, 2023

E-file Final Pretrial Order, Proposed Jury Instructions, Proposed Voir Dire Questions, and Trial Briefs and e-mail

(Trial Briefs are optional): June 1, 2023

Notice to Court Reporter of

Intent to Use Real-Time: June 1, 2023

Notice to I.T. Supervisor of Intent to Use CD-ROM or

Videoconferencing: June 1, 2023

Final Pretrial Conference: June 8, 2023 at 2:30 p.m.

The Court's previous Scheduling Order (Doc. 44) otherwise remains in full force and effect.

12

DATED this 30th day of November, 2022.

Dana L. Christensen, District Judge

United States District Court